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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,226	05/30/2007	Kotamballi Nagendra Murthy Chidambara Murthy	210172.402USPC	9359

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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,226	MURTHY ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *25-39* is/are pending in the application.

5a) Of the above claim(s) *25 and 26* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *27-39* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 25-39 are pending.

Applicant's election of Group II, claims 27-39, in the reply filed on 12/14/2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 25 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 27-39 are examined on the merits.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 28, 30, 32, 33, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Najarajan et al (Nagarajan et al, Chemical composition of the volatiles of Decalepis hamiltonii (Wight & Arn), Flavour and fragrance journal 2001; 16: 27-29, see IDS

filed on 6/29/2006), in view of Yanagimoto et al (Yanagimoto et al, Antioxidative activities of volatile extracts from green tea, oolong tea and black tea, Journal of Agricultural and Food Chemistry (2003), 51 (25), 7396-7401).

Najarajan et al teach D. hamiltonii root has a strong aromatic odour and its volatiles possess antimicrobial and insecticidal properties. On steam distillation, the fresh fleshy roots, collected from Karnataka, India, yielded a volatile oil (0.68%) from which 2-hydroxy-4-methoxybenzaldehyde crystallized out (96%). GC-MS analysis of the oil showed, besides the residual major component, the presence of benzaldehyde (0.017%), salicylaldehyde (0.018%), methyl salicylate (0.044%), benzyl alcohol (0.016%), 2-phenylethyl alcohol (0.081%), ethyl salicylate (0.038%), p-anisaldehyde (0.01%), and vanillin (0.45%), which are minor components but olfactorily and biologically significant (see Abstract). Najarajan et al teach the roots were cleaned and separated from the central woody core and peel to yield the fleshy material. They were cut into small pieces, and subjected to steam distillation with 3 L water. The steam condensate containing a crystalline solid material, was extracted with dichloromethane (thus a dichloromethane extract of Decalepis hamiltonii, thus with antioxidant activity) (see page 27, 2nd column, last paragraph).

Najarajan et al do not explicitly teach extracting medulla and peel of the tuberous root, neither do Najarajan et al teach the ratio of dichloromethane and tuberous root is 2:1, or the antioxidant activity of the extract.

Yanagimoto et al teach benzyl alcohol, which was proved to be an antioxidant, was identified both in a green tea extract and in a roasted tea extract (see Abstract). Yanagimoto et al teach benzyl alcohol was previously been proved to be an antioxidant. Benzyl alcohol inhibited

hexanal oxidation over 30 days at the level of 500 µg/ml. At a concentration of 400 µg/ml, benzyl alcohol inhibited magonaldehyde formation from blood plasma by 31%. Benzyl alcohol also inhibited methyl linoleate oxidant at a level of 200 µg/ml in the present study (page 7399, 2nd column, 2nd paragraph).

It is noted that since Najarajan et al teach extracting the claimed Decalepis hamiltonii root with the claimed solvent dichloromethane, the extract would necessarily have the claimed antioxidant and free radical scavenging activity. As further evidenced by Yanagimoto et al, benzyl alcohol (one of the component in the dichloromethane extract of Decalepis hamiltonii as taught by Najarajan et al) is an antioxidant.

It is noted that the roots would contain medulla and peel, and even if they don't, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to extract from the medulla and peel part of the root and expect to get the similar components with the rest of the roots. Choosing from a finite number of predictable solutions (such as different parts of the plant, such as peel of roots, medulla of roots, or the whole roots, etc.) would have been obvious because a person of ordinary skill has good reason to pursue the known options with his or her technical grasps. If this leads to the anticipated success, it is likely that the product is not of innovation, but of ordinary skill and common sense.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to vary the ratio between the solvent and the plant material. For instance, a larger amount of solvent tends to have a more complete and thorough extraction and requires a shorter extraction time, but the evaporation of solvent takes longer time and the cost of extraction increases due to the use of a larger amount of solvent. A light weighted plant material, such as

leaves, tends to demand a larger amount of solvent then roots or stem. Regarding to the claimed ratio of solvent versus plant material, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 27-30, 32, 33, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagarajan et al and Yanagimoto et al as applied to claims 27, 28, 30, 32, 33, and 35-37 above, and further in view of Strobel et al (US 5,445,809).

The teachings of Nagarajan et al and Yanagimoto et al are set forth above and applied as before.

The teachings of Nagarajan et al and Yanagimoto et al do not specifically teach the tuberous root is surface sterilized by washing with 70% alcohol.

Strobel et al teach the production of taxol from the yew tree (see Title). Strobel et al teach the yew wood provided is from the roots of a Yew tree. The roots are washed with sterile water and then treated with a solution of 70% ethanol to kill indigenous surface organisms (col 14, lines 5-10).

As evidenced by Strobel et al, it is a common practice to sterilize plant material with 70% alcohol to kill surface organisms. Therefore, it would have been *prima facie* obvious for one of

ordinary skill in the art at the time the invention was made to surface sterilized the tuberous root of Decalepis hamiltonii by washing with 70% alcohol.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 27, 28, and 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagarajan et al and Yanagimoto et al as applied to claims 27, 28, 30, 32, 33, and 35-37 above, and further in view of Giamperi et al (Giamperi et al, Composition and antioxidant activity of essential oil and ethanolic extract obtained from fresh flowers of Sambucus nigra, Rivista Italian EPPOS (2003), 35, 33-40).

The teachings of Nagarajan et al and Yanagimoto et al are set forth above and applied as before.

The combinations of Nagarajan et al and Yanagimoto et al do not specifically teach the claimed antioxidant activity range for a certain concentration of extract, and the antioxidant assay comprising evaluating beta-carotene bleaching, absorbance at 470 nm, and oxygenated aqueous beta-carotene linoleic acid emulsion in claims 31, 34 (a), 38, and 39 (b).

Giamperi et al teach antioxidant activity of these extracts was determined by a rapid spectrophotometric test involving the combined oxidation of beta-carotene and linoleic acid (see Abstract). Giamperi et al teach beta-carotene bleaching test and state that the technique is based on the measurement of bleaching of beta-carotene due to oxidation caused by degradation

products of linoleic acid. The model test mixture was prepared by dissolving 1 mg beta-carotene in 10 ml chloroform. Then 1 ml of this solution was added to a conical flask that containing 20 mg linoleic acid and 200 mg Tween 40. Chloroform was removed using a rotary evaporator at 40 degree C. Then 50 ml of distilled water was slowly added with vigorous agitation to form an emulsion at which was added the solution to assay that is BHT and essential oils previously dissolved in ethanol at concentration of 2 gr/L. The blank consisting of 20 mg linoleic acid, 200 mg Tween 40 and 50 ml distilled water was used to bring the spectrophotometer to zero. The conical flasks were shaken and absorbance measurements were made at 470 nm after the addition of the antioxidant solutions to the emulsion (thus % antioxidant activity = 100[1-(A° - AI)/A°0 – A'0)] wherein: A° = zero time absorbance at 470 nm of a sample comprising the extract having antioxidant activity and an oxygenated aqueous 13-carotene linoleic acid emulsion, A' = absorbance at 470 nm of the sample after incubation for a time period t, A°0 -- zero time absorbance at 470 nm of a control comprising the oxygenated aqueous beta-carotene linoleic acid emulsion without the extract, and A'0 -- absorbance at 470 nm of the control after incubation for the time period t). The flasks were placed in a water bath at 50 degree C, reading were at 30 min intervals to the point that the absorbance of control remained constant. At time t = 0 min the absorbance of beta-carotene at 470 nm was maximum (coefficient 1000). At time t = 150 min the minimum absorbance was observed for the control (0 coefficient) (emulsion + ethanol = control). All determinations were made in triplicate (page 35, cols 2 and 3).

As evidenced by Giamperi et al, using the claimed equation to measure antioxidant activity is well known in the art, and thus it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the antioxidant assay comprising

evaluating beta-carotene bleaching, absorbance at 470 nm, and oxygenated aqueous beta-carotene linoleic acid emulsion in claims 31, 34 (a), 38, and 39 (b) to measure the antioxidant activity of the dichloromethane extract of Decalepis hamiltonii roots. Regarding the limitation to the claimed antioxidant activity range for a concentration of extract, the antioxidant activity could be varied according to the collecting season and region of the plant material, and the extraction method of the plant material, including extraction time and extraction temperature.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655